

REMARKSRegarding the Status of the Claims:

Claims 1 – 21 are pending.

New claim 21 has been added.

No claims have been withdrawn from consideration.

Regarding the Claim Amendments presented in this reply:

The amendments to the claims do not add new matter. New claim 21 finds support in the specification on page 5, lines 12 – 14.

Regarding the Claim Rejections:

The Office action rejects:

- I. claims 1 – 4, 6 – 8, and 10 – 19 under 35 U.S.C §103(a) over US 5,073,379 to Klimesch et al. (hereinafter, “Klimesch”) and US 4,632,828 to Carli (hereinafter, “Carli”);
- II. claim 5 under 35 U.S.C §103(a) over Klimesch, Carli, and US 3,087,860 to Endicott et al. (hereinafter, “Endicott”); and
- III. claims 9 and 20 under 35 U.S.C §103(a) over Klimesch, Carli, and US 4,801,460 to Goertz et al. (hereinafter, “Goertz”).

Regarding Rejection I:

To support the rejection of claims 1 – 4, 6 – 8, and 10 – 19 under 35 U.S.C §103(a) over Klimesch and Carli, the Office action asserts that Klimesch teaches all the claimed features, except the “high level (50 – 99.4%) of crosslinked nonthermoplastic carrier.”¹ The Office action asserts that Carli describes systems consisting of drugs

¹ Page 4, lines 19 – 20 of the Office action mailed July 09, 2008.

loaded on hydrophilic, swellable, water-insoluble polymers, having a high polymer to drug ratio. Based on column 2, at lines 28 – 44 of Carli, the Office action asserts that the hydrophilic, swellable, water-insoluble polymers used in Carli provide certain advantages. Even though column 2, at lines 28 – 44 of Carli do not link these advantages to the polymer to drug ratio employed, but instead compare the Carli system to solid dispersions and inclusion compounds, the Office action asserts that a person of ordinary skill in the art would use the weight ratios of the Carli system in the Klimesch system in order to achieve the advantages described in column 2, at lines 28 – 44 of Carli.

In other words, the Office action proposes a combination of the teachings of Klimesch and Carli, wherein the amount of cross-linked nonthermoplastic carrier required by Klimesch would be increased based on distinct portions of Carli viewed in isolation from Carli as a whole. Applicants respectfully submit, according to MPEP §2141.02, the Carli “reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

As mentioned above, Carli does not provide a link between the advantages described in column 2, at lines 28 – 44, and the polymer to drug ratio employed. Thus, a person of ordinary skill in the art had no apparent reason to expect to achieve those advantages by employing the polymer to drug ratios described for Carli’s formulation. The Carli formulation is, after all, very specific. The Carli formulation must consist of MAP and at least one hydrophilic, swellable, water-insoluble polymer. Carli’s formulation does not include adjuvants. In fact, applicants respectfully submit that by using “consisting of” terminology, Carli explicitly rules out adjuvants. Carli does not provide a skilled artisan with an apparent reason to adopt a high polymer to drug ratio in a composition that includes adjuvants. Thus, no apparent reason existed to make the proposed combination.

Claim 2 requires the moldable cohesive composition to comprise 5 to 30% by weight of at least one thermoplastic polymer. Applicants respectfully submit that Carli makes clear that it is essential that no water-soluble polymer should be present during heating of the drug and cross-linked PVP. Carli is directed to a process for loading a

water-swellaable, water-insoluble polymer with methylhydroxyprogesterone acetate. At column 2, line 64, the importance of using a water-insoluble polymer is stressed. In other words, in addition to ruling out adjuvants in general, Carli strenuously rules out the thermoplastic polymer required by claim 2. Thus, a skilled artisan had no apparent reason to expect the advantages described by Carli to be obtainable according to the proposed combination, which would violate specific requirements of Carli.

A person of ordinary skill in the art had no apparent reason to arrive at a process that meets the requirements of new claim 21. Carli requires MAP and a polymer to be heated to the melting point of MAP. The melting point of MAP exceeds the maximum temperature allowed by new claim 21. A skilled artisan had no apparent reason to expect the advantages described by Carli to be obtained in a process that violates the specific requirements of Carli. Thus, no apparent reason existed to make the combination.

Finally, applicants respectfully submit that based on the teachings of the references, and without the benefit of the present application, a person of ordinary skill had no apparent reason to conclude that the proposed formulation would be suitable to be processed in a multi-screw extruder. The only information on record to indicate that such a formulation would be suitable to be processed in a multi-screw extruder, is found in the disclosure of the present application. Applicants respectfully submit that it would be inappropriate for Official notice to be taken on this issue. MPEP §2144.03 states, “Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known.”

As acknowledged on page 4, lines 19 – 20 of the Office action, Klimesch does not teach that a formulation comprising 50 – 99.4% of crosslinked nonthermoplastic carrier would have been suitable to be processed in a multi-screw extruder. Indeed, Klimesch does not contemplate such levels of crosslinked nonthermoplastic carrier at all.

Carli does not provide any apparent reason for a skilled artisan to conclude that the proposed formulation would be suitable to be processed in a multi-screw extruder. According to the claims of the present invention, a multi-screw extruder is used for

forming a moldable, cohesive composition. Carli does not relate to using a multi-screw extruder. Carli does not relate to forming a moldable, cohesive composition. The Carli heat-treated MAP crosslinked PVP system is, in fact, sieved (cf. Example 5 of Carli). A cohesive mixture cannot be sieved. A person of ordinary skill in the art had no apparent reason to consider the Carli system to be suitable to be processed in a multi-screw extruder, and, therefore, Carli does not provide any apparent reason for a skilled artisan to conclude that the formulation according to the proposed combination would be suitable to be processed in a multi-screw extruder. Since neither Carli nor Klimesh provide a person of ordinary skill with a reason to conclude that the proposed formulation would be suitable to be processed in a multi-screw extruder, the present rejection does not establish a *prima facie* case of obviousness.

Regarding Rejection II:

In the rejection of claim 5 under 35 U.S.C §103(a) over Klimesch, Carli, and Endicott, the Office action cites Endicott, because, as stated on page 10, at line 14, “Klimesch and Carli do not expressly teach sugar alcohols as adjuvants. Applicants do not concede that this feature would have been obvious in view of Endicott at column 3, lines 67 – 70. This rejection should be withdrawn in light of the discussion above with regard to the combination of Klimesch and Carli.

Regarding Rejection III:

In the rejection of claims 9 and 20 under 35 U.S.C §103(a) over Klimesch, Carli, and Goertz, the Office action cites Goertz, because, as stated on page 11 at lines 14 – 15, “Klimesch and Carli do not expressly teach the cooled composition that is comminuted and compressed to the dosage form.” Applicants do not concede that this feature would have been obvious in view of Goertz at column 5, lines 11 – 20. This rejection should be withdrawn in light of the discussion above with regard to the combination of Klimesch and Carli.

In Conclusion:

The present application is in condition for allowance. Applicants request favorable action in this matter. In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner is welcome to contact the undersigned by phone to further the discussion.

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Respectfully submitted,
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A handwritten signature in black ink, appearing to read "Michael P. Byrne", with a long horizontal flourish extending to the right.

Michael P. Byrne
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